IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO CASES IDENTIFIED IN **EXHIBIT A** TO DEFENDANTS' MOTION

PLAINTIFFS' RESPONSE TO MOTION AND MEMORANDUM TO EXCLUDE CERTAIN GENERAL OPINIONS OF BOBBY SHULL, M.D.

Plaintiffs hereby submit *Plaintiffs' Response to Motion and Memorandum to Exclude Certain General Opinions of Bobby Shull, M.D.* and in support of this Response, Plaintiffs state as follows:

I. INTRODUCTION

Robert Shull, M.D. (also referred to as "Bobby" or "Bob" and hereinafter "Dr. Shull") provided two expert reports in this matter: (1) a report on Defendant's Prolift and Prolift +M products (hereinafter the "Prolift Report"); and (2) a report on Defendant's Prosima product (hereinafter the "Prosima Report").[1] Dr. Shull is qualified and experienced in the fields of obstetrics and gynecology; he graduated from Tulane University School of Medicine in 1968 and completed his internship and residency at the University of Virginia. *See* Curriculum Vitae, attached as Ex. 3. In addition to having received numerous honors, awards, and serving on various committees and boards, Dr. Shull has been involved in 12 research projects; authored or co-

[1] For ease of reference, the Prolift and Prosima Reports are attached hereto as Exhibits 1 and 2, respectively.

authored 39 peer reviewed publications; authored or co-authored four (4) non-peer reviewed publications; drafted numerous book chapters, abstracts and discussions; and conducted various lectures and presentations. *See id.* Dr. Shull is unquestionably qualified by education, training, skill, and experience to provide the opinions set forth in his reports, opinions which are based upon sound methodology and proper application of sound methodology; and as such, both of Dr. Shull's expert reports pass scrutiny under a *Daubert* analysis.

Notwithstanding this, Defendants raise select challenges to Dr. Shull's opinions. Defendants' Motion should be denied as it: (a) makes no argument that any portion of Dr. Shull's Prosima Report should be excluded; (b) premises many arguments on a false presumption that Plaintiffs have only brought design defect claims; (c) improperly reserves issues for later briefing; (d) improperly incorporates specific causation issues; and (e) misapplies the *Daubert* standard with regard to any properly raised issues.

II. ARGUMENT

Defendants, in their Motion, incorporate by reference the standard of review for *Daubert* motions as set forth by this Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014). Plaintiffs agree that this Court's expression of the *Daubert* standard as set forth in *Huskey* is the proper standard of review.

A. No Portion of Dr. Shull's Prosima Report Should be Excluded as Defendant Sets Forth No Arguments Supporting Exclusion.

Defendants' Motion notes: "Although Dr. Shull submitted two reports, one for Prolift and one for Prosima, they are virtually identical. Therefore, in the interest of brevity, citations herein shall be generally limited to his Prolift report." Def.'s Motion at 1 n.1. Defendants then fail to cite to Dr. Shull's Prosima Report, while making substantive arguments in favor of exclusion, with the exception of a single citation in which Defendants set forth a specific causation argument (not

properly raised in their Motion), and in which Defendants improperly state they will brief the issue further through a motion in limine.[2] Def.'s Mot. at 10. Put simply, it is impossible for Plaintiffs to defend an attack on the Prosima Report when Defendants fail to include any specific argument to exclude any portion of that Report. Further, and more importantly, Defendants' decision to not brief their arguments on the Promisa Report prevents the Plaintiffs, and this Court, from considering whether any portion of the Prosima Report is properly excluded.

Defendants fail to realize that Dr. Shull's reports are not "virtually identical" and are different in critical ways, not the least of which entails the simple observation that the reports address *different* products. *Compare* Ex. 1 (addressing Prolift and Prolift +M) *with* Ex. 2. (addressing Prosima). By way of example, the Prosima Report offers many additional opinions not contained in the Prolift Report, including but not limited to: "There were no studies prior to introduction of the Prosima device demonstrating safety and efficacy of the Vaginal Support Device – Balloon Assembly;" "[t]he problems associated with the Prosima device are inherent in the concept and design and occur even when the device is placed properly;" and "[a]s an example of significant adverse events please refer to the case report by Hong describing massive internal bleeding associated with the Prosima and Gynemesh device." Ex. 2 at 2-3 (footnote omitted). Defendants' deposition of Dr. Shull buttresses the fact that his reports are different in substantive ways:

> Q. And as we walk through these reports today, your opinions are mostly identical for each of these products -- Prolift, Prolift +M, and Prosima -- except that where you characterized them differently in the report. For example, there will be paragraphs that are identical as we walk through the reports. Is that correct?
>
> A. Some things will be similar and some will vary depending on -- excuse me -- the scientific literature.

[2] *See* Argument *infra* Section II(C) for further discussion on Defendants' improper reservation of issues.

> . . .
>
> Q. . . . "Insertion of the device containing polypropylene mesh straps presents a specific risk and is inconsistent with sound pelvic reconstructive surgical procedures." That's different than the opinion that you had related to Prolift and Prolift +M. [Quote from Prolift Report omitted] So Prolift and Prolift +M, you had the insertion of a medical device with -- by using trocars. You don't use trocars with the Prosima. Right?
>
> A. Yes, sir, that's correct.

Ex. 4, Deposition of Dr. Shull dated March 15, 2016, at 13:22-14:1-5; 118:25-119:1-12 (underscore added). As such, Plaintiffs and the Court are left to guess as to what Defendants are arguing should be excluded from Dr. Shull's Prosima Report, and as Plaintiffs cannot respond to non-existent arguments, Dr. Shull's Prosima Report and associated opinions should not be excluded.[3]

B. No Portions of Dr. Shull's Reports Should be Excluded Based on Defendants' False Presumption that Plaintiffs Have Only Brought Design Defect Claims.

Defendants argue: "Any alleged comparative benefits of traditional approaches to treat POP are not relevant to Plaintiffs' design defect claims, because these approaches are not a medical device." Def.'s Mot. at 2. This is a specific causation assertion that may or may not be accurate depending on the substance of various state laws, which may or may not apply to the various plaintiffs.[4] Of course Plaintiffs do not concede this fact; but rather point out that Defendants' argument to exclude Dr. Shull's opinion "that non-synthetic mesh procedures are a safer alternative for the surgical treatment of POP," *Id.*, mischaracterizes Dr. Shull's opinion and,

[3] Plaintiffs anticipate that Defendants will argue that the admission of Dr. Shull's Prosima Report, resulting from Defendants' lack of argument, will allow this Report to escape *Daubert* review; however, this is a problem of Defendants' own making and "rulings *not to exclude* expert opinions are not dispositive of their admissibility." *Huskey*, 29 F. Supp. 3d at 734 (emphasis in original).

[4] *See* Argument *infra* Section II(D) for further discussion on Defendants' improper specific causation arguments.

assuming *arguendo* this characterization is correct, would only be successful if Plaintiffs *only* brought design defect claims.

First, Dr. Shull's opinion clearly states: "Traditional surgical repairs are effective. The medical literature does not show improved outcomes with the use of the Prolift or Prolift +M devices or any other transvaginally placed mesh." Ex. 1 at 2. Thus, Dr. Shull expresses two opinions: (1) that traditional surgery is effective; and (2) that the literature does not show improved "outcomes" when synthetic mesh is used. Defendants read meaning into Dr. Shull's opinion that is not present. When deposed, Dr. Shull confirmed the scope of his opinion:

> Q. So what you said in your general report is insertion of a mesh device containing arms involving the blind passage of trocars present specific risk and is inconsistent with sound pelvic reconstructive principles. And if it's inconsistent with sound pelvic reconstructive surgical principles, is it below the standard of care for a physician to do it?
>
> A. I didn't say that. I said exactly what's there. And in my opinion, I would not use these products. Other people feel differently, that they can safely use them, and the risks are less than the benefit.

Ex. 4 at 62:12-24. Therefore, Defendants have effectively created a phantom opinion with which to argue, and therefore, Defendants' request to exclude this opinion should be denied.

Moreover, even if Defendants have properly characterized Dr. Shull's opinion, which is not conceded and only presumed for the sake of argument, Plaintiffs have alleged much more than just a design defect claim. Plaintiffs' *First Amended Master Long Form Complaint and Jury Demand* alleges 18 causes of action, including but not limited to: negligence; fraud; fraudulent concealment; negligent misrepresentation; and breach of express warranty.[5] Dr. Shull's proffered

[5] Plaintiffs' *First Amended Master Long Form Complaint and Jury Demand* is available at: http://www.wvsd.uscourts.gov/MDL/ethicon/pdfs/FinalMasterComplaint.pdf. The Complaint is not attached here to avoid unnecessary duplication of filings.

opinions are relevant to any of these other causes of action, and as Defendants' argument is based on relevance, it should be denied on this additional basis.

Defendants' specific arguments with regard to Dr. Shull's phantom opinion are without merit. Defendants first cite *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 900 (E.D. W. Va. 2010) for the proposition that an "alternative design must not be an altogether different product." Def.'s Mot. at 2. However, *Torkie-Tork* applied Virginia state law to a negligent design defect claim, *Torkie-Tork*, 739 F. Supp. 2d at 899, and Defendants here offer no suggestion as to why a decision applying the law of a single state should control their argument as to Dr. Shull's *general* expert opinion. Moreover, in *Torkie-Tork*, plaintiff offered alternative designs that may have been so drastic as to constitute "it an entirely different product;" nonetheless, "the decision properly rests with a jury to determine . . . ." *Id.* at 900. As such, even if Defendants' argument is properly raised, Defendant has singled out a clear jury question. Moreover, the relief Defendants apparently seek, exclusion of Dr. Shull's phantom opinion on safer alternatives with respect to specific cases, should be sought in case-specific *Daubert* motions, through submission of appropriate jury instructions, or other such procedures, but not in a general *Daubert* motion.

Finally, Defendants argue: "The notion that traditional surgical approaches are safer alternatives to Prolift/Prosima is premised on the assumption that all mesh products are unsafe." Def.'s Mot. at 3. Of course, as described above, this argument mischaracterizes Dr. Shull's opinion. Moreover, Dr. Shull never opines that "all mesh products are unsafe." In fact, Dr. Shull and his associates in his practice use certain mesh products in their practice, such as midurethral slings. Ex. 4 at 50:10-16. As such, Dr. Shull does not hold the opinion that "all mesh products are unsafe" and Defendants' arguments built on this premise, *i.e.*, that Dr. Shull actually "takes issue with the choice of Plaintiffs' physicians recommending a medical device" are misplaced and

inapposite. For these additional reasons, Defendant's request to exclude Dr. Shull's phantom opinion should be denied.[6]

C. Defendants Improperly Reserve Issues for Later Briefing.

Defendants argue, in a section that properly belongs in a case specific motion, and is addressed in greater detail below, that: "although Dr. Shull criticizes the design of Prolift . . . the Court should exclude such design opinions with respect to specific Plaintiffs in which there is no evidence of any injury caused by that specific design [citation to reports omitted]. Defendants are also submitting a motion in limine about this issue." Def.'s Mot. at 9-10. It is unclear why Defendants are filing a motion in limine on an issue that clearly belongs in a case-specific *Daubert* motion. If Defendants missed their deadline to file any case-specific *Daubert* motion, they should not be allowed to circumvent the court-ordered deadlines by re-labeling the argument as a motion in limine. Moreover, the Court has already stated that this type of issue will not be considered in a motion in limine:

> The court expects the parties to file motions in limine only for the purpose of precluding highly prejudicial statements in opening or closing statements or questions at trial that, once heard by the jury, cannot easily be cured by an instruction to disregard. The court will not provide advisory opinions on the admissibility of evidence a party may offer at trial and will summarily deny those motions as premature.

Pretrial Order No. 217, Section B(4). Thus, as Defendants have indicated they are submitting a motion in limine clearly meant to determine the "admissibility of evidence," well after the deadline

[6] Defendants' citation to *Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. 2013) is problematic for two reasons: (1) it was decided in the summary judgment context in a specific case, not at the *Daubert* phase attacking an expert's general opinion; and (2) Nevada state law governed the outcome in that case and there is no indication that Nevada state law should govern any part of Defendants' Motion.

set by the Court for *Daubert* motions, Defendants should be precluded from filing any such motions.

Defendants also request to: "reserve for trial any objections to Dr. Shull's testimony that are based merely on a narrative summary of Ethicon documents." Def.'s Mot. at 12. Defendants do not argue for exclusion of this evidence, and therefore, none of Dr. Shull's testimony should be excluded on this basis. While Defendants cite to 18 pages of Dr. Shull's Prolift Report, there is no way for Plaintiffs, or this Court, to determine with specificity what Defendants consider to be a "narrative summary." Should Defendants subsequently attempt to develop this argument in their yet-to-be-filed motion in limine, this attempt should be denied. As noted above, to the extent Defendants desire to raise other objections at trial, such as Rule 403 objections or other evidentiary objections, with regard to opinions not screened out through a *Daubert* analysis, this Court has already affirmed that ability.

D. Defendants' Specific Causation Arguments Should not be Considered.

Without identifying a specific Plaintiff or letting Plaintiffs know to which case the argument applies, defendants make case specific arguments in their general *Daubert* motion. *See* Def.'s Mot. at 2 n.2 (Defendants apply its argument regarding "safer alternatives" specifically to five named plaintiffs); *Id.* at 9-10 (Defendants argue: "if there is no evidence that the mesh in a particular Plaintiff's device degraded or otherwise deformed, then Dr. Shull's general opinions . . . should be excluded in that case . . . ."); *Id.* at 10 (Defendants argue: "to the extent that Dr. Shull intends to testify about patient populations of which each respective Plaintiff is not a member, any such testimony is irrelevant . . . ."); *Id.* at 11 (Defendants argue: "[t]he Court should also preclude Dr. Shull from testifying about conditions that a respective Plaintiff has not sustained . . . .") (underscore added). It is unknown why Defendants set forth these

arguments when Pretrial Order No. 217 states: "For the filing of *Daubert* motions on general causation issues, the parties are instructed to file one *Daubert* motion per expert in the main MDL . . . [s]pecific causation *Daubert* motions, responses and replies must be filed in the individual member cases." Pretrial Order No. 217, Section B(3). As such, the Court should not consider any case specific arguments set forth by Defendants in their motion. Presumably, any of Defendants' case-specific arguments were made via separate *Daubert* motions in individual cases or Defendants chose to waive these arguments. Further, Plaintiffs cannot respond to these arguments, as there is no indication as to which case(s) each argument applies.

E. Defendants' Properly Raised Arguments are Without Merit.

The remainder of Defendants' Motion raises general causation arguments that are without merit.

1. Opinions Regarding Clinical Trials.

Defendant argues that Dr. Shull's opinions regarding the existence or non-existence of clinical trials of Prolift and Prolift +M should be excluded. Def.'s Mot. at 3-5. While Defendants argue that Dr. Shull should not be allowed to opine on Defendants' lack of pre-market studies of its products, the fact remains that Defendants did not undertake any proper clinical studies. *See* Ex. 1 at 24 ("From my review of the materials referenced, I was impressed by the clear absence of any systematic approach on the part of Ethicon with regard to clinical testing of the products prior to placing the products on the market"); *Id.* at 25 ("There were no proper randomized controlled trials with institutional review board (IRB) approval performed in the United States or abroad prior to selling these products") (citing Defendants' *own* document which stated: "Based upon the Gynemesh Prolene Soft mesh's product characteristics, intended clinical indications, and the use

of existing polymer materials, additional pre-clinical functionality testing is not required") (underscore added).

Thus, Defendants seek to exclude Dr. Shull's opinion, *i.e.*, whether or not testing was performed, when their own internal documents state it was not required and there is no evidence any proper clinical testing was ever performed. Further, Defendants cite *Green v. General Motors Corp.* (a New Jersey state case) for the proposition that a lack of testing or a flaw in the design process is not, standing alone, a design defect. Once again, Defendants miss the boat as they once again fail to acknowledge that Plaintiffs have brought many other claims besides design defect for which the existence or non-existence of testing constitutes clearly relevant and material evidence. For example, these facts may directly inform whether Defendants acted negligently or not. Additionally, this is a case specific argument that will only apply to some – yet to be specified by Defendants – Plaintiffs depending on the applicable state law.

Next, Defendants argue that Dr. Shull does not have specialized knowledge about the testing that Defendants should have performed; however, this argument underscores Defendants' misunderstanding of Dr. Shull's ultimate opinion on this matter: "As a physician, I expect companies to provide me with complete and accurate information. This cannot be accomplished without sufficient data." Ex. 1 at 26.

This relatively unremarkable opinion does not require specialized knowledge of the testing Defendants should have performed, rather it only requires knowledge of whether or not the testing was in fact completed (information which was provided to Dr. Shull) together with Dr. Shull's vast years of clinical experience, *see generally* Ex. 3, which inform his opinion on what type of information he thinks he should be provided. Therefore, Defendants' citation to *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *15 (S.D. W. Va. Apr. 28, 2015) in which Dr. Shull's

opinions on the "appropriate testing" were excluded, is readily distinguished. Here, Dr. Shull seeks to give the opinion that testing was not performed, and from his clinical perspective, he does not think medical device manufacturing companies can provide complete and accurate information without sufficient data derived from testing. This opinion is akin to Dr. Shull's opinions on product labels, which were allowed by this Court. *Id.* at *16 ("I also find that Dr. Shull's forty years of experience, along with his evaluation of medical literature . . . forms a reliable basis for this testimony") (citing *Kumho Tire Co.*, 526 U.S. at 156 (stating that an "expert might draw a conclusion from a set of observations based on extensive and specialized experience")).

Finally, Defendants argue that Dr. Shull may only speculate as to what the non-existent testing, if it had been performed, would have revealed. Dr. Shull need not, and does not, speculate in his report: "The serious complications associated with transvaginally placed mesh kits are now well-known to surgeons practicing in this area of female pelvic reconstructive surgery, and well-described in the medical literature." Ex. 1 at 9. These opinions are well cited in Dr. Shull's reports. *See* Ex. 1 at 6-9. Therefore, Defendants' Motion seeking to exclude Dr. Shull's opinions as to Defendants' testing of Prolift and Prolift +M, or lack thereof, should be denied.

2. Opinions Regarding Adverse Event Reporting.

Defendant next argues that Dr. Shull's opinions related to adverse event reporting should be excluded. Def.'s Mot. at 5. Here, Defendants again overstate the scope of Dr. Shull's proffered opinion, which is stated in his Prolift Report as: "After the products were used in general clinical setting, Ethicon did not systematically monitor their products or evaluate physician feedback." Ex. 1 at 3. Thus, Dr. Shull is not offering an opinion as to the *nature* or *quality* of the adverse event reporting that should have occurred, but rather, he is stating that it did not occur. This opinion is not conjecture and is well cited in his Prolift Report. *See* Ex. 1 at 26 ("Ethicon failed to establish

a data registry for Prolift . . . [a] registry would have been a very useful tool to track the outcomes of patients who underwent the Prolift procedure and permanent Prolift mesh implantation . . . Ethicon resisted a proposal to start a registry in Australia . . . .") (citing Defendants' own internal documents including an email that stated: "Consequently, if none of our competitors are keeping registries, our complication data may appear increasingly accurate but with decreasing appeal"). Thus, Defendants' citations to *In re Diet Drugs* and *Hines v. Wyeth* are readily distinguished as in those cases the experts sought to opine on the nature, quality or effect of the adverse event reporting, or completely lacked an explanation for the basis of their opinions; and therefore, Defendants' Motion to exclude Dr. Shull's opinion in this regard should be denied.

3. Opinions Regarding the Regulatory Process.

Defendants seek to exclude Dr. Shull's opinions relating to the regulatory process. Def.'s Mot. at 6. Defendants argue that Dr. Shull is unqualified to opine on "certain risks" not disclosed in the Section 510(k) process. This nearly identical argument, was made with regard to Dr. Shull, and was rejected by this Court in *Carlson v. Boston Scientific Corp.*: "Instead, Dr. Shull will testify about the risks he perceives Uphold poses to patients, and he will opine that the Uphold DFU did not convey these risks to physicians. A urogynecologist like Dr. Shull is qualified to make this comparison." 2015 WL 1931311, at *16. Here, Dr. Shull seeks to assert the same opinion, that is, he will opine on the risks that Prolift and Prolift +M pose to patients and note that Defendants did not list these risks on their Section 510(k) application, and therefore, his opinion in this regard should not be precluded.[7]

[7] Defendants also argue that Dr. Shull be precluded from testifying about conclusions that the FDA "supposedly made." Def.'s Mot. at 6. However, Dr. Shull opines: "The FDA reached many of these same conclusions in its white paper . . . ." Ex. 1 at 28. As such, Dr. Shull is not noting "supposed[]" conclusions, but actual conclusions, and his opinion in this regard should not be excluded.

4. Opinions Regarding Physician Training.

Defendants also seek to exclude Dr. Shull's opinion regarding whether or not Defendants provided appropriate training to physicians. Def.'s Mot. at 6. Dr. Shull's proffered opinion is stated as: "Ethicon . . . did not properly train these physicians in the unique aspects of patient selection and patient counseling of long-term sequelae [conditions caused by injury] of trocar-based meshed kits." Ex. 1 at 3. Dr. Shull's opinion is well grounded in his experience: "I have reviewed the Ethicon Instructions for Use (IFU) and patient and doctor brochures for these products. Reviewing the information contained in these documents is something I do on a regular basis in my practice and in my capacity as an educator of medical students . . . these documents . . . do not include the severity and frequency of the complications . . . do[] not provide information regarding contraindications to the use of the product in women with fibromyalgia, painful bladder syndrome, or other chronic pain conditions." Ex. 1 at 10. As Dr. Shull is an educator of medical students, and the complications caused by Defendants' mesh products are well cited elsewhere in his opinion, *see* Ex. 1 at 6-9, Dr. Shull is qualified by education, experience, skill, and reliable application of methodology to opine on proper training and Defendants' Motion should be denied in this regard. Moreover, Defendants' citation to *Cisson v. C.R. Bard, Inc.* is inapposite as that case involved the exclusion of Dr. Shull's opinions in a specific case where the opinion was "not applied to the facts of the case." 948 F. Supp. 2d 589, 614 (S.D. W. Va. 2013). Any such argument in these cases in best left for the case specific *Daubert* motions, not here.

5. Opinions Regarding Marketing.

Defendant next argues that Dr. Shull's opinions regarding marketing should be precluded. Def.'s Mot. at 7. Again, Defendants cite to the inapposite *Cisson* decision for support despite the fact that decision was case-specific. Moreover, Dr. Shull's opinion that Defendants improperly

marketed their devices to "all physicians" is grounded in his experience that a physician should have a "minimum skill set" to use the product and that it would not have been unreasonable for Defendants to state: "In order to use this properly, you should have this amount of knowledge to use the product I am making and use it successfully." Ex. 4 at 88:11-24. This type of experience-based opinion is analogous to Dr. Shull's opinions this Court found acceptable in *Carlson*, and therefore, Defendants' Motion should be denied as to marketing opinions. 2015 WL 1931311, at *16 ("I also find that Dr. Shull's forty years of experience, along with his evaluation of medical literature . . . forms a reliable basis for this testimony") (citing *Kumho Tire Co.*, 526 U.S. at 156 (stating that an "expert might draw a conclusion from a set of observations based on extensive and specialized experience")).[8]

6. Opinions Regarding Purported Legal Conclusions.

Defendants also argue that "certain of Dr. Shull's opinions are legal conclusions," and therefore, should be excluded. Def.'s Mot. at 7. However, Defendants only cite to *one* of these purported legal conclusions in which Dr. Shull opines: "From a clinical perspective, Ethicon did not exercise due diligence . . . ." Ex. 1 at 3. Legal professionals do not have a monopoly over terms such as "due diligence," and Dr. Shull's use of a qualifier, "[f]rom a clinical perspective," proves this observation. Dr. Shull elaborates in his deposition that his basis for forming the opinion that Defendants did not exercise due diligence, from a clinical perspective, is: "[t]he clinical outcomes. The patients -- patients have been harmed." Ex. 4 at 82:20-25. Thus, Dr. Shull's opinion is not a

[8] Defendants also argue that Dr. Shull's opinion regarding Defendants' formation of a special interest group should be excluded. Def.'s Mot. at 7. Again, Dr. Shull's opinion on this matter is not conjecture, but rather a factual observation that is well cited and should not be excluded. *See* Ex. 1 at 13.

legal conclusion and should not be excluded. As for the remainder of Dr. Shull's purported legal conclusions, Defendants do not cite to these opinions so Plaintiffs are unable to respond.

7. Opinions Regarding Biomaterials.

Defendants additionally seek to exclude Dr. Shull's opinions "concerning biomaterials, such as product design and degradation" on the basis that he is "not qualified and his opinions are unreliable." Def.'s Mot. at 7. However, Dr. Shull is qualified to opine on these matters as he has "personally examined, diagnosed and treated approximately one hundred patients with mesh complications and removed some mesh from at least 70 women." Ex. 1 at 1. Moreover, Dr. Shull's Prolift Report relies on extensive literature detailing "chronic inflammation and foreign body reaction, bacterial contamination, shrinkage and contraction, fibrosis and scarring, embrittlement, nerve involvement, deformation, and degradation." Ex. 1 at 6-7. Dr. Shull has also viewed videos demonstrating how the "arms of the mesh can become string-like and are no longer flat . . . [not] only during implantation but after, the Prolift and Prolift +M arms are put under a considerable amount of strain, which may ultimately lead to mesh curling, roping, and deformation." Ex. 1 at 8. In his deposition, Dr. Shull testified: "From a clinical standpoint, I feel I am an expert on evaluating people who have had biomaterials put in." Ex. 4 at 63:7-9. This assertion is difficult to rebut given Dr. Shull's education, experience, skill and reliance on medical literature. As such, Dr. Shull is qualified to opine on this subject.

Again, Defendants' citation to *Cisson* is unavailing as this Court actually found "Dr. Shull is qualified to render opinions on such issues [product design, testing, and materials]." 948 F. Supp. 2d at 612. In *Cisson*, the Court found Dr. Shull's opinions had no reliable basis because they relied only upon personal experience and internal documents. Here, Dr. Shull's opinions are grounded in clinical experience, internal documents, *and* medical literature and videos on Prolift and Prolift

+M implantation. As such, Dr. Shull's opinions on these issues are reliable and distinguishable from those proffered in *Cisson* and should not be excluded. Moreover, Defendants seek exclusion of a "number of opinions concerning biomaterials," Def.'s Mot. at 7, but only specify opinions related to product design, degradation, and deformation. As such, Plaintiffs cannot respond to the "number of other opinions" and those opinions should not be excluded.

8. Opinions Regarding Small Pore, Heavy Weight Mesh.

Defendants seek to exclude Dr. Shull's opinion that "[s]maller pore, heavier weight meshes, like Gynemesh, are thought to intensify" adverse reactions as unsupported and unreliable. Def.'s Mot. at 8. Defendants' argument completely ignores the panoply of citations that precede this statement including at least two articles dealing with pore size and the weight of mesh. *See* Ex. 1 at 7 nn.12, 14. Defendants go on to cite *Conklin v. Novartis Pharmas. Corp.* and *In re AlloDerm Litigation*, respectively, for the propositions that: (1) an expert could not testify under Texas law about an alternative safe design and (2) plaintiffs must prove with empirical evidence or reliable data that an alternative design is actually safer. But again, these arguments, even if based upon proper statements of law, are not controlling as Plaintiffs have alleged many more claims than just a design defect claim and these arguments are necessarily case-specific. As such, Defendants' assertion that Dr. Shull's opinions are "naked conclusion[s] of the expert" is incorrect, ignores the content of Dr. Shull's Prolift Report, and therefore, Dr. Shull's opinions in this regard should not be excluded.

9. Opinions Regarding IFUs.

Defendants argue that Dr. Shull's opinions regarding IFUs should be excluded. Def.'s Mot. at 10. This argument is already addressed in Section II(E)(3) *supra* and need not be restated here. However, it should be noted that Defendants cite to *Cisson* for support without acknowledging

that this Court specifically held Dr. Shull qualified to opine on what risks were missing from the IFU in *Carlson*. *See* Section II(E)(3) *supra*. Additionally, Defendants attempt to extend this argument to excluding Dr. Shull from opining that: "Ethicon did not inform doctors as to which patients were poor candidates for the Prolift procedure." Def.'s Mot. at 10. Dr. Shull's opinion is not conjecture but is well cited in his report and supported by Defendants' own documents, *see* Ex. 1 at 12 n.34, and as such, should not be excluded.

10. Opinions Regarding Defendants' Knowledge and Conduct.

Defendants make a final argument that Dr. Shull's "report is replete with other statements about Ethicon's alleged knowledge and conduct, Def.'s Mot. at 11; however, Defendants fail to cite even a single instance of these "statements." As such, Plaintiffs are unable to respond this argument and none of Dr. Shull's opinions should be excluded on this basis.

III. CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully request Defendants' Motion be denied in its entirety.

Dated: May 9, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, a true and correct copy of this Response, and exhibits, was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

/s/ Aimee H. Wagstaff, Esq.